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To: OMB_peer_review@omb.eop.gov

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Subject: Revised Information Quality Bulletin on Peer Review

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725 17th St. NW, Room 10201
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Dear Dr. Schwab,

Along with Dr. Marolyn Parson, I submit the attached comments of the National Association of Home Builders on the Revised Information Quality Bulletin on Peer Review.

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ADVOCACY GROUP

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Submitted via email to OMB_peer_review@omb.eop.gov

May 28, 2004

Re: Proposed Bulletin on Peer Review and Information Quality

Dear Dr. Schwab:

The National Association of Home Builders (NAHB) appreciates this opportunity to comment on the “Revised Information Quality Bulletin on Peer Review” (69 Fed. Reg. 23230 *et seq.*, April 28, 2004). NAHB represents more than 215,000 builders and associate members organized in more than 800 affiliated state and local associations in all fifty states, the District of Columbia, and Puerto Rico. NAHB’s membership not only includes firms that construct and supply single-family homes, but also apartment, condominium, and commercial and industrial builders, as well as land developers and remodelers. NAHB members are responsible for the construction of approximately 80% of all new homes built in the U.S. and are regularly required to comply with a plethora of federal regulations promulgated by the Department of Labor, Department of Housing and Urban Development, Department of Transportation, Department of Energy, Veterans’ Administration, Environmental Protection Agency, Army Corps of Engineers, Forest Service, Bureau of Land Management, Fish and Wildlife Service, National Marine Fisheries Service, U.S. Trade Representative, Bureau of the Census, and others.

The National Association of Home Builders (NAHB) supports the principle that policy decisions should be based on sound science, and supports independent peer review of scientific and technical information as a crucial step to ensure that the science is sound. NAHB supported the first proposal for peer review enthusiastically, while suggesting the strengthening of some provisions. However, the current proposal is a disappointing retreat from the high standards proposed originally.

The current proposal suffers from several flaws that reduce the contribution it could make toward the accomplishment of the purposes of the Information Quality Act. Most significantly, the effect of the guidelines is severely limited by the extent of the exemptions and alternative processes. Where the guidelines do apply, the agencies are given such broad latitude in their peer review processes that observable standards are nearly absent. The application of guidelines involves a new term “scientific assessment” referring to an evaluation of a body of knowledge, but this leaves unclear what treatment

is to be given to purely factual—rather than evaluative—material. The guidelines offer advice, but few requirements to prevent agencies and consultants from developing business relationships that may impair the independence required of external reviewers. In the only section where the guidelines use the mandatory language of “shall,” the term is applied in reference to situations where the agency must make a judgment call within its discretion.

These general shortcomings and other specific concerns are presented in detail below along with NAHB’s recommendations.

Dissemination

The current proposal exempts documents from peer review when they have been distributed for peer review purposes (Section I(3)). The basic premise has an unassailable logic, that papers can’t be peer reviewed until they have been passed to the reviewers. However, NAHB urges OIRA to strengthen that section to ensure that no other circulation of the information is allowed, at least until the peer review is complete.

Relationship Between the Selection of Reviewers, the Review Process, and Policy Issues

Peer review is not independent of nor irrelevant to policy. The sole reason for peer review is to have a sound scientific basis for a policy decision. If there were no policy decision to be made, the peer review process would be irrelevant. Thus peer review is part of a political process in a democratic society, and it is subject to the same strictures that control government. The proposal gives great weight to scientific expertise, which is important, surely. But as this is a government process, there is another criterion which the process must satisfy, and that is fairness. The process must be actually fair and it must appear to be fair. It cannot appear to be stacked in one direction or another. If the process does not appear to fair, its scientific accuracy is useless, because it will not be credible. Any policy based on apparently unfair research will lack the legitimacy that justice demands. Any such regulation may be struck down legally as arbitrary and capricious, politically by Congressional repeal of agency over-reaching, or popularly by resistance among the regulated. Compliance is much lower when the regulated have no faith in the legitimacy of the regulation or the process that produced it. The Office of Information and Regulatory Affairs (OIRA) notes quite correctly that “peer review, if performed fairly and vigorously, can build consensus among stakeholders” (page 10 Bulletin, OIRA web page version, April 15, 2004).

Therefore, it is imperative that the reviewers reflect not only scientific diversity, but also stakeholder diversity. Reviewers are isolated scholars who seek arcane truths in an intellectual vacuum. They are whole people with whole minds, and they seek truth using the ideological lenses they have developed. These lenses or frameworks influence the kinds of questions they ask and what criteria satisfy them for and answer. People from differing stakeholder positions are most likely to bringing differing scientific approaches, simultaneously satisfying the need for intellectual balance and social fairness. In particular, no stakeholders should be systematically excluded, except the agency whose work is under review. The agency experts must be excluded—even under

Section II—because the review must be independent and external. Contrary to OIRA recommendations, NAHB proposes that the reviewers be selected to represent a balance stakeholder interests.

NAHB supports the guidance under “Conflicts” and “Independence,” Sections III(2)(b,c), to the extent that they warn of continuous or repeated research or review relationships with the agency. Those warnings should be extended to Section II. All regulations deserve sound science, reviewed by impartial experts.

NAHB believes that the greatest scientific or technical expertise in a subject is likely to lie in the regulated community. The large chemical and pharmaceutical firms certainly have extensive research programs, employing many learned scientists with deep understanding of the scientific issues. It would be a waste to exclude such knowledge from the debate in the early stages, when the agency is trying to learn the consensus of the scientific community. NAHB urges OIRA and the agencies to include experts from the regulated community as reviewers.

NAHB commends OIRA for reminding reviewers that they are to examine and determine facts; they are not to advise on policy. However, the Bulletin contains an extensive discussion about scientific uncertainty, and part of that uncertainty is selection of research method and the formulation of the research agenda. The reviewers’ policy views are likely to affect their evaluations of research methods, even though they are being completely sincere. They just answer questions according to the way they see the world, and their policy opinions are part of the worldview. Therefore NAHB submits that peer review panels should be balanced for policy perspectives, even though the reviewers are not to address policy issues.

NAHB fully supports OIRA’s recommendation that review be rotated among those qualified to act as reviewers. The proposal seems to accept the comments from the community of professional reviewers that there is a dearth of qualified reviewers. At the public meeting held at the National Academies to discuss the first proposed guidelines, there was an implicit suggestion that experience at reviewing makes one a better reviewer. If that unlikely proposition is indeed true, NAHB suggests the agencies take up a suggestion made at that meeting and start to include fresh faces in each review panel. And again, NAHB repeats its observation that the expertise to review research is not as great as the expertise to conduct it; many new PhDs—fresh from the dissertation process—would be able and willing to review research for soundness of method, suitability of data, and consistency with current theory.

NAHB supports public nomination of expert reviewers. Though not excluded by the discussion, stakeholder organizations may also be aware of experts who would contribute valuable insight to the review process. Conversely, nomination by a learned society does not guarantee objectivity. Some organizations purport to be learned or research organizations, but in fact they exclude certain points of view systematically. They may know of experts, but they should be treated as stakeholders or advocacy groups, rather than learned societies.

NAHB believes it is unlikely that qualified, independent experts will not be available, and strongly opposes the use of agency employees as peer reviewers (except for those hired occasionally to be reviewers). Agency employees are neither external nor independent. The agency is a policy making body, and use of internal reviewers violates the reviewers' charge to separate policy and scientific issues. If the agency uses any internal reviewers, it should announce to the public that the science underlying the proposed rule has not been peer reviewed. "Peer review" within the agency is not meaningful peer review at all.

The Peer Review Process

The proposal adds a new category of "highly influential scientific assessments," but it has no category of "highly influential scientific information." Thus scientific information is reviewed only under the looser standards of Section II, not under the more rigorous standards of Section III. NAHB believes it should be made clear that any scientific or technical information that satisfies the conditions of Section III(1) is subject to the guidelines of Section III; Section III is not limited to assessments. Agencies must be reminded that if they disseminate the scientific assessment, they are held to data quality requirements for the information contained therein, including any facts alleged in the articles reviewed in the scientific assessment. This distinction appears to elevate scientific literature over scientific fact, which would be lamentable. Although the guidance states that all the requirements of Section II apply to Section III, NAHB recommends that the guidance be clarified so that "highly influential scientific assessments" includes "highly influential scientific information" explicitly.

NAHB fully supports the proposal that the charge to the reviewers be developed before the reviewers are selected. The agency should determine the scientific questions to be answered, then find people to answer them. Choosing reviewers first may change the questions to reflect the reviewers' particular expertise.

Transparency is fundamental to both fairness and scientific inquiry. In general, NAHB supports transparency in government and opposes secrecy. For the peer review process to perform its role in building consensus, it must be done in the open as far as is practical. At the very least, NAHB believes it is essential to have the names of the reviewers released to the public if the information is disseminated. If the information is not disseminated, NAHB believes it still may be necessary to reveal the identities of the reviewers, especially if their comments were the reason the information was not disseminated. In fact, the public must be able to review the comments of each reviewer, so the objectivity, integrity, and utility of that reviewer's comments can be evaluated

In general, NAHB believes that panels are more likely to produce a useful critique of the information than individual letters could provide. A panel allows the reviewers themselves to determine their areas of agreement and disagreement, rather than leaving that to the agency and the public to infer. Since different minds are bound to disagree on some things, a panel may produce a consensus among the reviewers, which would be more useful guidance than three separate reports that seem at odds with each other.

Panels also afford each reviewer some degree of confidentiality, which encourages candor. Technologies like conference calls and internet capabilities make panel discussions feasible, even when the panelists are distant from each other. NAHB recommends that peer reviews be done by panel whenever it is practical to do so.

Public participation in the review process presents an untidy concept. However, NAHB believes the public should see the reviewers' comments and identities no later than the opening of the comment period on the policy proposed by the agency, and as soon as the agency disseminates the information. In the normal course, NAHB submits that public participation in expert review seems self-contradictory, as the public are not experts. However, in some cases the reviewers may need to seek public input, or the public stake may be so large that members of the public should be able to watch the review process and submit questions and suggestions. This would be especially true in cases where the underlying science is highly uncertain and controversial, and in cases where the consequences of the decision are very large. Though the consequences are not a scientific issue, scientific certainty becomes more important when the scientific decision has greater ramifications. In these cases, OMB should favor transparency and utility to call for a review process that can be monitored by the public and which the public can join, perhaps to the point of holding public hearings on the record.

Section V, Peer Review Planning, is a welcome addition. Section V maintains, or even increases transparency, and it may allow citizen involvement earlier in the regulatory process. However, it appears to be meant as a substitute for agency guidelines that were advocated in the first peer review proposal. The advantage of guidelines is that they commit the agency to some level of consistency in its treatment of different issues. NAHB recommends that Section V be retained, but NAHB believes the public interest would be served if each agency would craft additional guidelines appropriate to its own specialization, in order to diminish the opportunity for arbitrary or unsound action. NAHB recommends that the requirement of individual agency guidelines be re-established.

Alternative Procedures

NAHB opposes inclusion of the new Section IV, "Alternative Procedures." First, it could be interpreted to mean that findings of the National Academy of Sciences are conclusive on issues of fact and research method. If that is the intention, then the section is an illegal delegation of administrative authority. The law accords opinions of the National Academy no more deference than any other expert opinion. This argument holds whether the agency is taking administrative notice of Academy research in accord with Section IV(i), or if the agency submitted research for review under Section IV(ii). Furthermore, NAHB submits that Section IV(iii) introduces unnecessary arbitrariness to the administrative process by releasing agencies from the written, public regulations of Sections II and III, replacing them with *ad hoc* procedures that have never been submitted for public comment. NAHB believes that any need for flexibility is more than met by Sections II and III, and NAHB urges that Section IV be removed in its entirety.

Exemptions and Waiver

NAHB is troubled by the extensive exemptions (Section VIII) that reduce the applicability of peer review to a broad variety of situations. Obviously, public peer review cannot be required where the subject matter must be kept secret for legitimate national security reasons, or where peer review requirements would delay emergency action to prevent or combat a clear and present danger to the public health or safety. However, NAHB asserts that even in these cases, peer review may be appropriate later, when the emergency has passed, particularly in the context of whether rules should remain in force, or whether they should be used again in similar circumstances. NAHB urges OMB to consider this possibility and to provide explicitly for post-emergency review.

It is important to distinguish between information itself and the program created to assemble and disseminate the information. No one suggests that Census results be peer reviewed, but its data collection methods may call for extensive peer review. The development of the American Community Survey is a case in point. This Census product has undergone substantial review, but its reports will get none, under Exemption 6. NAHB raises no objection to Exemption 6, as long as this distinction is borne in mind.

However, NAHB believes other exemptions exclude more than they need to. For example, Exemption 7 excludes information “generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures or taxes[.]” Many of these actions are routine and they are excluded appropriately, such as the statistics in the monthly *Federal Reserve Bulletin*. Also, it is probably bad practice to require, e.g., the Federal Reserve to disclose the economic basis for its conduct of monetary policy. However, the Federal Reserve, the Federal Housing Finance Board, the Comptroller of the Currency, and the Office of Thrift Supervision all issue regulations subject to the Administrative Procedure Act, the Paperwork Reduction Act, and the Information Quality Act. These regulations are the result of a deliberative process that relies heavily on theoretical and empirical work in statistics and the social and behavioral sciences. Their decisions determine the way the banking system is run, controlling the security of people’s savings, the availability of credit, and the rates of inflation and of capital formation. These decisions should be based on sound science, and that science needs peer review. The welfare of many households is influenced by the decisions based on these analyses, and they need the same level of protection from arbitrary decisions. Therefore, NAHB calls for removal of this exemption, except for routine activities performed under programs approved through the regular processes of the Administrative Procedure Act.

Exemption 3 excludes agency adjudication or permit proceedings, unless the *agency* determines the dissemination is based on novel science or technology *and* it is likely to have precedent-setting influence. Re-iterating its comments on the first proposal, NAHB submits that permit and adjudication proceedings may have substantial effects on large numbers of people. When a dam is proposed for license, a pharmaceutical manufacturer faces adjudication over the labeling or effectiveness of its product, or real estate developers apply for incidental take permits under the Endangered

Species Act, the science underlying those permits and adjudications should be sound. All the reasons OIRA gives for peer review apply in these cases as well. This is not an argument that the permit itself be reviewed, but there should be adequate review of the influential scientific on which the permit decision is based. This review may not be necessary each time a permit is considered based on the same information, but if the science is uncertain or the social and economic consequences are great, the science should be validated before policy decisions are made. Further, NAHB urges OIRA to make it completely clear that the exemption does not apply to a policy that sets up permit or adjudication criteria or defines such a program.

Exemption 8 applies to rules that “materially alter” entitlements, grants, user fees, or loan programs. If the policy decision makes a material alteration to a government policy, the decision should not be based on shoddy information. If, for example, the Department of Housing and Urban Development decides to curtail Section 8 housing assistance, because it has decided that the program does not improve the housing quality of the poor; that decision must be based on facts in an administrative record. To the extent that those facts consist of influential scientific or technical information—especially from the social or behavioral sciences—that information should be as sound as the information that influences any other government decision.

Exemption 8 is also inconsistent internally. It exempts information disseminated for rules that “materially alter” entitlements and so forth, but it adds that influential scientific information disseminated in connection with non-routine rules is not exempt. A material alteration could not be routine. Minor alterations could be routine, but to describe a change as “material” is to imply it is out of the ordinary, thus not routine. Therefore the exemption is vague, so vague its meaning cannot be ascertained. For the reasons in this paragraph and the one preceding it, NAHB recommends that Exemption 8 be eliminated entirely, or restricted to decisions that make *no* material change in entitlements, grants, and so forth.

Finally, Section VII, “Safeguards and Waivers,” allows waiver of the peer review requirements “where warranted by a compelling rationale.” Presumably, any such rationale would be substantially the same as the “good cause” exception to the Administrative Procedure Act, section 553(b)(3)(B). NAHB urges OIRA to change the language to reflect the fact that the conditions are the same.

Conclusion

The current revised peer review guidelines are a step forward toward putting administrative decisions on a sound scientific basis. Their adoption will be an improvement in the regulatory process, if they are followed in good faith. However, it is unfortunate that they fall so far short of what they could have done. They still leave room for the same cadre of professional experts to establish cozy relationships with the agencies by rubber-stamping whatever the agencies suggest. While the agencies and experts will have to be somewhat more public about it, and those who are unjustly regulated may have some more concrete grounds for remedy, these guidelines will do

Dr. Margo Schwab

June 1, 2004

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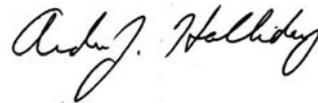
little to accomplish the goals of the statute mandating high quality in the information disseminated to the public.

NAHB supported the earlier, stronger proposal enthusiastically, even urging strengthening some provisions. The current proposal is weaker; *a fortiori* NAHB would like this one strengthened even more. Nonetheless, this proposal does put in place guidelines for performing an important function in maintaining the quality of data used in federal decision making. Adoption of these guidelines should result in more peer review, particularly among agencies that tended not to use it before. In all agencies, the quality of the peer review should rise.

In the best world, the major contribution of these guidelines is not to the protection of the regulated, but rather to the advancement of the missions of the various federal agencies. Following these guidelines will improve the knowledge on which they rely, and they can make better decisions. Wholehearted adoption of even these mild guidelines is not likely soon, because they call for critique of one's work by strangers. People do not care for criticism in general, and there is no reason to think federal employees are particularly different from the rest of us.

NAHB urges OIRA to keep close watch on how the peer review process changes as a result of this bulletin. If agencies fail to follow the guidelines, they must be pressured to comply. Further, NAHB suggests OIRA revisit the peer review issue after the agencies have had time to implement the guidelines. At that time, OIRA should decide whether it is necessary to change the guidelines in order to accomplish the statutory objectives of the Information Quality Act or to improve the confidence of the public in the accuracy and fairness of the regulatory process.

Sincerely,



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Regulatory Counsel



Marolyn J. Parson, Ph.D.
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